

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. 2005N-0148]

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Author	A. Corbin

**Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Extralabel Drug Use in Animals**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

**DATES:** Fax written comments on the collection of information by *[insert date 30 days after date of publication in the Federal Register]*.

**ADDRESSES:** OMB is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202-395-6974.

**FOR FURTHER INFORMATION CONTACT:** Denver Presley, Office of Management Programs (HFA-250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-1472.

**SUPPLEMENTARY INFORMATION:** In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

**Extralabel Drug Use in Animals—21 CFR Part 530 (OMB Control No. 0910–0325)—Extension**

*Description:* The Animal Medicinal Drug Use Clarification Act of 1994 (AMDUCA) (Public Law 103–396) allows a veterinarian to prescribe the extralabel use of approved new animal drugs. Also, AMDUCA permits FDA, if it finds that there is a reasonable probability that the extralabel use of an animal drug may present a risk to the public health, to establish a safe level for a residue from the extralabel use of an animal drug and to require the development of an analytical method for the detection of residues above that established safe level. Although to date, we have not established a safe level for a residue from the extralabel use of any new animal drug, and therefore have not required the development of analytical methodology, we believe that there may be instances when analytical methodology will be required. We are, therefore, estimating the reporting burden based on two methods being required annually. The requirement to establish an analytical method may be fulfilled by any interested person. We believe that the sponsor of the drug will be willing to develop the method in most cases. Alternatively, FDA, the sponsor, and perhaps a third party may cooperatively arrange for method development. The respondents may be sponsors of new animal drugs, State or Federal government, or individuals.

In the **Federal Register** of May 3, 2005 (70 FR 22884), the agency published a 60-day notice requesting public comment on the collection of information. No comments were received.

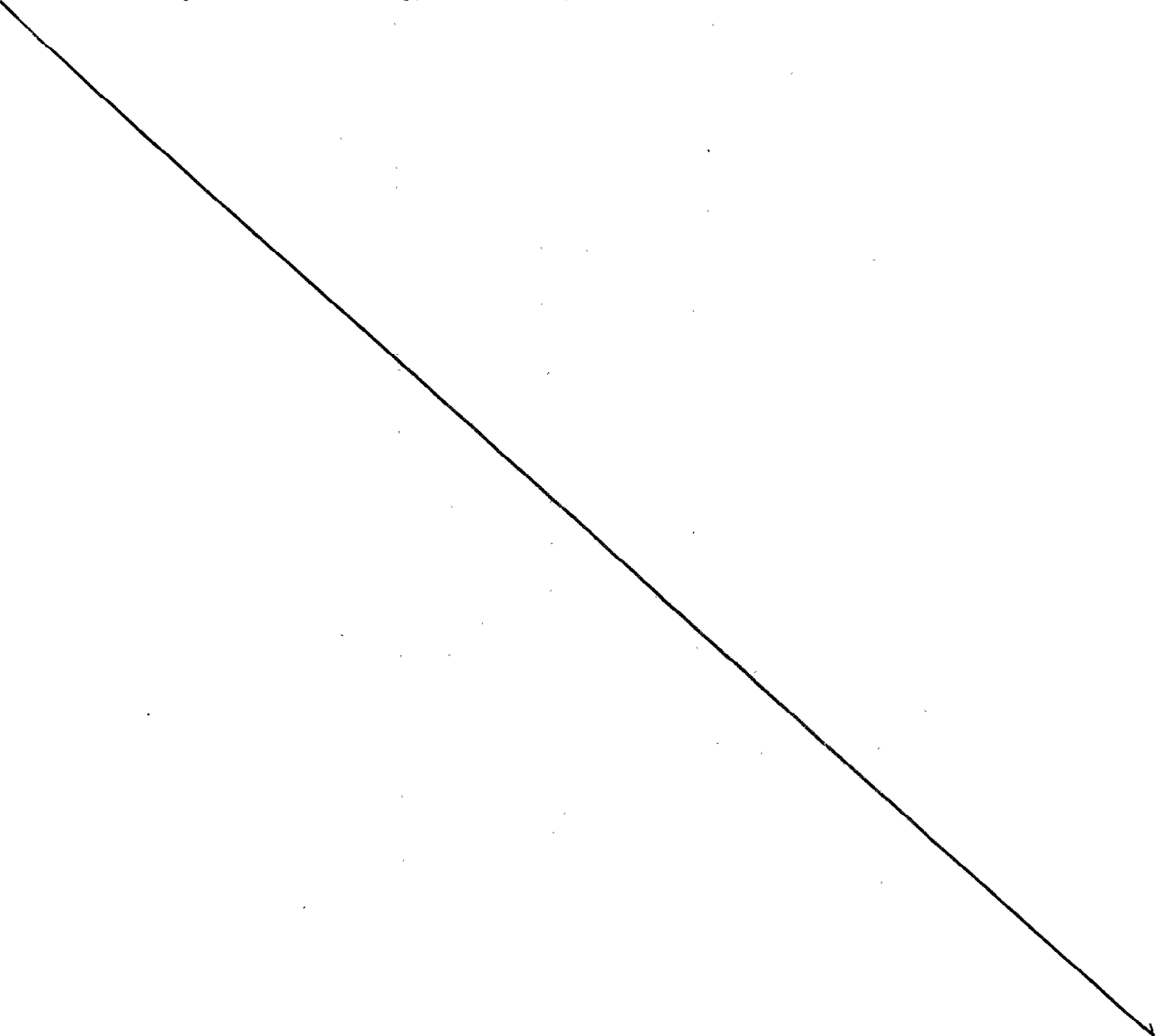
FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
530.22(b)	2	1	2	4,160	8,320

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

The Center for Veterinary Medicine (CVM) has not found circumstances to require the establishment of a safe level and subsequent development of an analytical methodology. However, CVM believes there will be instances when an analytical methodology will be required.



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Dated: \_\_\_\_\_

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September 22, 2005.

*Jeffrey Shuren*

Jeffrey Shuren,  
Assistant Commissioner for Policy.

[FR Doc. 05-????? Filed ??-??-05; 8:45 am]

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